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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/836,781	04/17/2001	Michael P. Whitman	11443/45	6776

26646 7590 09/05/2003

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EXAMINER

TRAN, LOUIS B

ART UNIT PAPER NUMBER

3721

DATE MAILED: 09/05/2003

16

Please find below and/or attached an Office communication concerning this application or proceeding.

NK

Office Action Summary

Application No.

09/836,781

Applicant(s)

WHITMAN ET AL.

Examiner

Louis B Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) [X] Responsive to communication(s) filed on 20 June 2003.
2a) [X] This action is FINAL. 2b) [] This action is non-final.
3) [] Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) [X] Claim(s) 1-44 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) [] Claim(s) _____ is/are allowed.
6) [X] Claim(s) 1-44 is/are rejected.
7) [] Claim(s) _____ is/are objected to.
8) [] Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) [] The specification is objected to by the Examiner.
10) [] The drawing(s) filed on _____ is/are: a) [] accepted or b) [] objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
11) [] The proposed drawing correction filed on _____ is: a) [] approved b) [] disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
12) [] The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) [] Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) [] All b) [] Some * c) [] None of:
1. [] Certified copies of the priority documents have been received.
2. [] Certified copies of the priority documents have been received in Application No. _____.
3. [] Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
14) [] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) [] The translation of the foreign language provisional application has been received.
15) [X] Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) [] Notice of References Cited (PTO-892)
2) [] Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) [] Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) [] Interview Summary (PTO-413) Paper No(s) _____.
5) [] Notice of Informal Patent Application (PTO-152)
6) [] Other: _____

DETAILED ACTION

1. This action is in response to applicant's amendment, Paper No. 13, received on 06/20/2003.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1, 12, and 23 have incorporated the new limitation, "a memory unit housed inside the surgical instrument and adapted for complete insertion in the body with the instrument". It is unclear if the memory unit is adapted for complete insertion in the body or the surgical instrument is adapted. The memory unit 174 does not seem to be physically adapted for insertion in the body as shown in Figure 9A of applicant's invention.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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5. Claims 1, 4-6, 10, 12, 15-18, 23, and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (5,383,874) in view of Denen et al. (5,400,267).

With respect to claims 1, 12, and 23, Jackson et al. anticipates the use of a surgical instrument configured for complete insertion into a body for use with an electro-mechanical surgical device comprising a coupling configured to couple the surgical instrument with the electromechanical surgical device and a memory unit 88 housed inside the surgical instrument and adapted for complete insertion in the body with the instrument, said memory unit configured to store data representing at least one parameter, data representing a usage, a serial number relating to the surgical instrument (as in claim 1, 12, and 23), wherein the data is readable by a control system 76 of the electro-mechanical surgical device as in column 6, line 24 (as in claim 4, 15, and 26), wherein the at least one parameter includes at least one of a usage data as in column 8, lines 60-65, a serial number data and a type of the surgical instrument as in column 8, line 62 (as in claim 10), wherein the control system is configured to limit usage of the surgical instrument in accordance with the usage data as in column 9, lines 13-30 (as in claim 16), but does not explicitly show wherein the coupling includes a data connector configured to connect the memory unit with the electro-mechanical surgical device.

Jackson et al. has assumed a data connection is available to transfer information from a memory unit to a surgical device. However, to further show the well-known and common use of data connectors in the surgical art, Denen et al. teaches the use of

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wherein a coupling 14 includes a data connector configured to connect the memory unit with the electro-mechanical surgical device (as in claim 1), wherein the data connector is configured to electrically and logically connect the memory unit to a control system of the electro-mechanical surgical device (as in claim 5, 17, and 27), as described in column 7, lines 34 to 67, wherein the coupling is configured to detachably attach the surgical instrument to the electro-mechanical surgical device as seen in Figure 2 (as in claim 6, 18, and 28), for the purpose of connecting a device to a control apparatus and power supply.

Therefore, it would have been obvious to one having ordinary skill in the art to provide Jackson et al. with a coupling and a data connector in order to transfer information from a memory unit to a control unit.

Moreover, with respect to applicant's new limitations in claims 1, 12, and 23, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138.

6. Claims 2, 3, 7-9, 11, 13, 14, 19-22, 24, 25, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jackson et al. (5,383,874) in view of Denen et al. (5,400,267) in further view of Adams et al. (6,119,913).

The modified device of Jackson et al. discloses the invention substantially as claimed including the above discussed but does not show at least one connector

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configured to removably couple with at least one rotatable drive shaft of the electro mechanical surgical device.

However, Adams et al. teaches the use of at least one connector configured to removably couple with at least one rotatable drive shaft 722 of the electro mechanical surgical device as in column 10, lines 5-30 and Figure 15 (as in claim 2, 13, and 24), a first connector and a second connector, each of the connectors being configured to removably couple with a respective drive shaft 722', 724' of the electro-mechanical surgical device described in column 10, lines 10-25 (as in claims 3, 14, and 25), wherein the surgical instrument includes a surgical stapler and cutter instrument (as in claim 7, 19, and 29), wherein the surgical stapler and cutter instrument includes an anvil portion 48 and staple driver and cutter portion (as in claim 8, 20, and 30), an anvil drive shaft configured to open and close the anvil portion and a stapler drive shaft configured to drive the staple driver and cutter portion as in the abstract of Adams et al. (as in claim 9, 21, and 31), for the purpose of transmitting a rotation force to a surgical instrument as in column 10, lines 5-30.

Moreover, Adams also teaches at least one driven element 40 and a gear 44 arrangement configured to couple a drive shaft 22 of the electro-mechanical surgical device to the at least one driven element, the gear arrangement being configured to convert a rotation of the drive shaft to drive the at least one driven element at a torque, as inherently achieved by any gear arrangement, exemplified in Figure 2 (as in claim 11, 22 and 32)

Although Adams does not explicitly state the rotation is high-speed rotation for high torque output, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select high speed rotation and torque over standard or slow rotation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Therefore, it would have been obvious to one having ordinary skill in the art to provide a rotatable drive shaft in order to transfer force to a surgical instrument for operation.

7. Claim 33-41 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (6,119,913).

With respect to claim 33, Adams et al. teaches an electro-mechanical surgical device, a surgical instrument configured for complete insertion into a body for use with the electro-mechanical surgical device at least one rotatable drive shaft 22 removably attachable to the surgical instrument, a motor arrangement configured to rotate the at least one rotatable drive shaft from a proximal end thereof as described in column 6, line 35, a first gear arrangement disposed at a distal end of the rotatable drive shaft 44, and at least one element 40 driven by the gear arrangement, wherein the gear arrangement is configured to convert a rotation of the rotatable drive shaft to drive the at least one driven element at a torque as discussed in column 7, line 13, and wherein the first gear arrangement includes at least one of a spur gear arrangement, a planetary gear

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arrangement, a harmonic gear arrangement, cycloidal drive arrangement, and an epicyclic gear arrangement as see in Figure 15 (as in claim 43).

Adams also show the surgical system wherein the surgical instrument 718 is removeably attachable to the distal end of the rotatable drive shaft, the surgical instrument including the at least one element as best seen in Figure 15 (as in claim 34), wherein the first gear arrangement is disposed in the surgical instrument as in Figure 15 (as in claim 35), wherein the surgical instrument includes a circular surgical stapler attachment as seen in Figure 15A and 15 9 (as in claim 36), wherein the at least one element includes at least one of an anvil 720 of the circular surgical stapler attachment and a staple driver and cutter 38 of the circular surgical stapler attachment in the embodiments of Figure 15 and 5 (as in claim 37), wherein the at least one rotatable drive shaft includes a first rotatable drive shaft 722 and a second rotatable drive shaft 724 as described in column 10, line 24, wherein the at least one element includes a first element driven by the first rotatable drive shaft and a second element driven by the second rotatable drive shaft seen in Figure 15, and wherein the gear arrangement includes a first gear system configured to convert rotation of the first rotatable drive shaft to drive the first driven element at a torque and a second gear system configured to convert a rotation of the second rotatable drive shaft to drive the second driven element at a torque (as in claim 38).

Although Adams does not explicitly state the rotation is high-speed rotation for high torque output, it would have been obvious to one having ordinary skill in the art at the time the invention was made to select high speed rotation and torque over standard

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or slow rotation, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Adams teaches wherein the motor arrangement includes a first motor configured to rotate the first rotatable drive shaft and a second motor configured to rotate the second rotatable drive shaft in column 6, lines 34-36, where items 25 and 27 may be electric motors (as in claim 39), wherein the surgical instrument is removably connectible to the distal end of the first and second rotatable drive shafts, the surgical instrument including the first and second elements as seen in Figure 15 (as in claim 40), wherein the first element includes an anvil and second element includes a staple driver and cutter(as in claim 41).

8. Claims 42 and 44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Adams et al. (6,119,913) in view of Hooven (5,433,721).

The modified device of Adams et al. discloses the invention substantially as claimed including a first gear arrangement including at least one of a spur gear arrangement, a planetary gear arrangement, a harmonic gear arrangement, cycloidal drive arrangement, and an epicyclic gear arrangement but does not specifically teach a second gear arrangement disposed between the motor arrangement and the at least one rotatable drive shaft, the second gear arrangement configured to convert a high torque transmitted by the motor arrangement to rotate the at least one rotatable drive shaft at the high speed.

However, Hooven teaches the use of a second gear arrangement disposed between the motor arrangement and the at least one rotatable drive shaft, the second gear arrangement configured to convert a high torque transmitted by the motor arrangement to rotate the at least one rotatable drive shaft at the high speed (as in claim 42), a second gear arrangement including at least one of a spur gear arrangement, a planetary gear arrangement, a harmonic gear arrangement, cycloidal drive arrangement, and an epicyclic gear arrangement (as in claim 44), for the purposes of reducing torque as in column 8, line 46 Figure 3.

Therefore, it would have been obvious to one having ordinary skill in the art to provide gear reductions for various operations.

Conclusion

9. Applicant's remarks have been fully considered but are deemed non-persuasive. Applicant has relied upon functional language in the form of "adapted to" to place the application in condition for allowance. As cited above, it has been held that the recitation that an element is "adapted to" perform a function is not a positive limitation but only requires the ability to so perform. It does not constitute a limitation in any patentable sense. *In re Hutchison*, 69 USPQ 138

Applicant contends that Adams et al. has no suggestion that the control wires are "removably coupled" to connectors on the stapling head. Initially, it must be noted that the features upon which applicant relies (i.e., removably coupled to connectors on the stapling head) are not recited in the rejected claim(s). Although the claims are

interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The language of the claim 2 reads, "connector configured to removably couple with at least one rotatable drive shaft..". Column 10, lines 10-25 describe the connectors of Adams et al. Specifically, "control wires are rigid and terminate inside the stationary part with coupling ends such as a keyway or hex socket coupling".

Applicant has requested the examiner provide evidence of record that supports a motivation for changing the speed rotation of Adams et al. The examiner has relied upon *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980) to show that finding optimum values of operation (such as speed or torque optimum values) are within the grasp of one of ordinary skill in the art. Furthermore, applicant has not defined any values for what high torque and high speed is to encompass. Since claims are given their broadest reasonable interpretation, Adams et al. can easily be described as high speed rotation for high speed torque output device.

For the reasons above, the grounds of rejection are deemed proper.

10. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Louis B Tran whose telephone number is 703-305-0611. The examiner can normally be reached on 8AM-6PM Monday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rinaldi I Rada can be reached on 703-308-2187. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1148.

lbt



Rinaldi I. Rada
Supervisory Patent Examiner
Group 3700